REMARKS

Claims 8-10, 12-15, 41-44, 52-53, 56-57, 59-64, 66-92, and 94-98 are pending in this application. By this Amendment, claims 8, 12-14, 41, 44, 53, 66, 80, 82-84, 89, and 92 are amended, claims 95-98 are added, and claim 93 is cancelled without prejudice or disclaimer. Support for the claims can be found throughout the specification, including the original claims, and the drawings. Withdrawal of the rejections in view of the above amendments and the following remarks is respectfully requested.

I. Allowable Subject Matter

The Examiner is thanked for the indication that claims 63-64, 67-70, 85, and 88 are allowed, and that claims 13-15, 42, 44, 56, 61, 66, 72, 75-76, 78, 80-82, 84, 87, 90-91, and 93 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. It is noted that objected to claims 80 and 82 are already in independent form, and have been amended in response to the Examiner's comments. Accordingly, it is respectfully submitted that independent claims 80 and 82, as well as objected to claim 81 which depends from independent claim 80, are also in condition for allowance. However, for the reasons set forth below, claims 13-15, 42, 44, 56, 61, 66, 72, 75-76, 78, 84, 87, 90-91, and 93 have not been rewritten in independent form at this time.

II. Informalities

A. Specification

The Office Action objects to the specification as failing to provide proper antecedent basis for the controller as recited in claims 44 and 84. It is respectfully submitted that the amendments made to claims 44 and 84 are responsive to the Examiner's comments, and thus the objection should be withdrawn.

B. Claims

The Office Action objects to the recitation of a drug reservoir/pump in claims 8, 12-14, 41, 80, and 82-83. Claims 8, 12-14, 41, 80, and 82-83 have been amended to recite "a drug reservoir and pump," as this element is configured to both retain and to pump a drug as required. It is respectfully submitted that the amendments to these claims are responsive to the Examiner's comments, and thus the objection should be withdrawn.

The Office Action objects to claim 66 under 37 CFR 1.75(c) as being of improper dependent form. The amendments made to claim 66 are responsive to the Examiner's comments, and thus the objection should be withdrawn.

C. Drawings

The Office Action objects to the drawings under 37 CFR 1.83(a), alleging that the drawings do not show every feature of the invention specified in claims 82, 44, and 84.

With respect to claim 82, the Examiner's attention is drawn to Figures 29A-29B and 30. More specifically, these figures show a plurality of microinfusion catheter 1005 configured with a

plurality of individually controllable ports 1007, wherein each of the microinfusion catheters 1005 is functionally coupled to a manifold 1009, which is functionally coupled to a drug supply line 1011, which is functionally coupled to a pump 1013. It is respectfully submitted that the drawings show each of the features specified in claim 82, and thus meet the requirements of 37 CFR 1.75(c). Accordingly, the objection should be withdrawn.

With respect to claims 44 and 84, the controller feature has been deleted from these claims. It is respectfully submitted that the drawings meet the requirements of 37 CFR 1.75(c), and thus the objection should be withdrawn.

III. Rejections Under 35 U.S.C. 103(a)

The Office Action rejects claims 53, 60, and 86 under 35 U.S.C. 103(a) as being unpatentable over Schulman et al., U.S. Patent No. 5,531,679 (hereinafter "Schulman"). It appears it was also the Examiner's intention to reject claim 62 over Schulman. The rejection is respectfully traversed.

Independent claim 53 recites, *inter alia*, a plurality of microinfusion catheters extending though the macrocatheter and movably disposed non-coaxially side by side with respect to one another, wherein each of the plurality of microinfusion catheters is configured to receive a drug, and wherein an end portion of each of the plurality of microinfusion catheters is configured to extend beyond an end of the macrocatheter so as to infuse the drug into the hypothalamus of a patient. Schulman neither discloses nor suggests such features.

Schulman discloses a fluidic infusion system for introducing a liquid chemical into an area surrounding an end of a probe 10, including a lumen 12 which delivers the liquid chemical to a plurality of openings 22 formed in a wall 24 of the probe 10 for infusion into the bloodstream 39. Schulman discloses in Figure 6 a plurality of lumens 12' extending from a proximal end 14 to a distal end 16 of the probe 10. A plurality of reservoirs R and corresponding pumps P deliver a liquid chemical through a manifold 26' to the lumens 12', and each of the lumens 12' transports a different fluid to one of the openings 22' formed in the probe 10.

The plurality of lumens 12' disclosed by Schulman, most appropriately compared to the plurality of microinfusion catheters recited in independent claim 53, are all contained within the probe 10, and do not move within the confines of the probe 10, nor do they extend beyond the confines of the probe 10. In turn, the probe 10, which houses the plurality of lumens 12', is most appropriately compared to the macrocatheter recited in independent claim 53. Once the lumens 12' deliver the liquid chemical to the various openings in the probe 10, the probe 10, and not the lumens 12', delivers the liquid chemical to the bloodstream 39 of the patient. In contrast, ends of the plurality of microinfusion catheters recited in independent claim 53 extend beyond an end of the macrocatheter, thus allowing the individual microinfusion catheters, and not the macrocatheter, to infuse the drug into the hypothalamus. Thus, it is respectfully submitted that Schulman neither discloses nor suggests the plurality of microinfusion catheters as recited in independent claim 53.

Additionally, the fluidic infusion system disclosed by Schulman is specifically designed for infusing liquid chemicals into the bloodstream of a patient, and Schulman does not disclose or suggest that this system could be easily or readily adapted for use in the brain, nor that it would be beneficial to do so. In contrast, the plurality of microinfusion catheters recited in independent claim 53 are specifically configured to, *inter alia*, infuse a drug into the hypothalamus of a patient.

For at least these reasons, it is respectfully submitted that independent claim 53 is allowable over Schulman, and thus the rejection of independent claim 53 under 35 U.S.C. 103(a) over Schulman should be withdrawn. Rejected dependent claims 60 and 62, as well as objected to claims 56 and 61, are allowable at least for the reasons set forth above with respect to independent claim 53, from which they depend, as well as for their added features.

Independent claim 86 recites, *inter alia*, at least one electrode configured to sense electrical activity of the hypothalamus. Schulman neither discloses nor suggests such features.

Schulman further discloses an active area 27 of a sensor 19 which is exposed through a window 25 in the wall 24 of the probe 10. This active area 27 of the sensor 19 measures glucose concentration, oxygen, pH, temperature, and the like (see column 6, lines 1-3 of Schulman). The active area 27 of the sensor 19 is not configured to sense electrical activity of the hypothalamus, as recited in independent claim 86.

Further, as set forth above, the fluidic infusion system disclosed by Schulman is specifically designed for infusing liquid chemicals into the bloodstream of a patient, and

Schulman does not disclose or suggest that this system could be easily or readily adapted for use in the hypothalamus, as recited in independent claim 86, nor that it would be beneficial to do so. Additionally, Schulman does not disclose or suggest that the sensor 19 could be adapted to sense any type of electric activity, let alone electrical activity of the hypothalamus, as recited in independent claim 86, nor that it would be beneficial to do so.

Accordingly, it is respectfully submitted that independent claim 86 is allowable over Schulman, and thus the rejection of independent claim 86 under 35 U.S.C. 103(a) over Schulman should be withdrawn. Objected to claim 87 is allowable at least for the reasons set forth above with respect to independent claim 86, from which it depends, as well as for its added features.

The Office Action rejects claims 8, 12, 41, 52-53, 57, 71, 73, 77, 79, 92, and 94 under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al., U.S. Patent No. 5,772,629 (hereinafter "Kaplan"). The rejection is respectfully traversed.

Independent claim 8 recites, *inter alia*, wherein at least one microinfusion catheter of said plurality of microinfusion catheters comprises a plurality of drug delivery ports arranged such that each drug delivery port of the plurality of drug delivery ports is configured to deliver a drug to a separate site within the hypothalamus. Kaplan neither discloses nor suggests such features.

Kaplan discloses a system for inhibiting blockage or localized thrombosis in a blood vessel after an angioplasty procedure. Kaplan's system includes a sleeve infusion catheter 110, including an infusion sleeve 112 with a radially expansible portion 113, a manifold 114 connected to the infusion sleeve 112, and a shaft 116 connected to the manifold 114. The

infusion sleeve 112 includes four infusion lumens 126, with corresponding infusion ports 128 formed over a distal portion of the expansible portion 113 of the sleeve 112. An inflatable balloon B may be introduced into a central receptacle 124 of the infusion sleeve 112 and extend outward through the distal tip of the sleeve 112. The balloon B may be inflated while the sleeve 112 is retracted, thus allowing the expansible portion 113 of the sleeve 112 to be expanded.

The combination of the balloon catheter BC and the infusion catheter 110 are introduced into a coronary artery in a patient's heart H through a guide wire GW of a guiding catheter GC until the balloon B is positioned within a target site. After an angioplasty procedure is conducted, the sleeve 112 is advanced over the balloon catheter BC until the radially expansible portion 113 is positioned over the balloon B, and the balloon is inflated to engage the infusion ports 128 against an inner wall of the coronary artery (see column 8, lines 46-51 and 62-65 of Kaplan). A TFPI solution is then delivered through the ports 128 to preclude blockage after completion of the procedure.

The four infusion lumens 126 and their corresponding infusion ports 128 are fixed with respect to the expansible portion 113 of the sleeve 112 as the catheter 110 is positioned in the patient's artery. More specifically, the lumen structure begins with a single circular lumen 150 formed in the shaft portion of the catheter 110, and transitions into a crescent shaped transition lumen region 152 as it enters the manifold 114. The path of the single lumen then transitions into an annular lumen 144 as it approaches the exit of the manifold 114, and into four infusion lumens 126 in the infusion sleeve 112 (see column 7, line 55 – column 8, line 7 and Figures 2-6

of Kaplan). The four lumens 126 deliver the TFPI solution to their respective ports 128 for delivery to a target site, and Kaplan does not disclose or suggest that any one of the four fixed lumens 126 may be rearranged so as to deliver the solution to a site outside the target site, nor that the grouping of ports 128 associated with any one of the 4 fixed lumens 126 are capable of each delivering the solution to a separate site. Thus, Kaplan neither discloses nor suggests the plurality of microinfusion catheters as recited in independent claim 8.

Additionally, the infusion catheter disclosed by Kaplan is specifically designed for infusing liquid chemicals into the artery of a patient after an angioplasty procedure, and Kaplan does not disclose or suggest that his infusion catheter could be easily or readily adapted for use in the brain, nor that it would be beneficial to do so. In contrast, the plurality of microinfusion catheters recited in independent claim 8 are specifically configured to, *inter alia*, be inserted into the hypothalamus of a patient's brain, and the plurality of drug delivery ports deliver a drug to a separate site within the hypothalamus.

For at least these reasons, it is respectfully submitted that independent claim 8 is allowable over Kaplan, and thus the rejection of independent claim 8 under 35 U.S.C. 103(a) over Kaplan should be withdrawn. Rejected dependent claims 12, 41, and 52, as well as objected to claims 13-15, and 42, are allowable at least for the reasons set forth above with respect to independent claim 8, from which they depend, as well as for their added features.

Independent claim 53 recites, *inter alia*, a plurality of microinfusion catheters extending though the macrocatheter and movably disposed non-coaxially side by side with respect to one

another, wherein each of the plurality of microinfusion catheters is configured to receive a drug, and wherein an end portion of each of the plurality of microinfusion catheters is configured to extend beyond an end of the macrocatheter so as to infuse the drug into the hypothalamus of a patient. Kaplan neither discloses nor suggests such features.

As set forth above, the four infusion lumens 126 disclosed by Kaplan are clearly a fixed part of the structure of the infusion sleeve 112, as shown by the cross sectional views taken at various locations along the length of the infusion sleeve 112 and shown in Figures 2-6 of Kaplan, and are not movably disposed within the catheter 110. Thus, Kaplan neither discloses nor suggests the plurality of microinfusion catheters as recited in independent claim 53.

Further, as set forth above, the infusion catheter disclosed by Kaplan is specifically designed for infusing liquid chemicals into the artery of a patient after an angioplasty procedure, and Kaplan does not disclose or suggest that his infusion catheter could be easily or readily adapted for use in the brain, nor that it would be beneficial to do so.

For at least these reasons, it is respectfully submitted that independent claim 53 is allowable over Kaplan, and thus the rejection of independent claim 53 under 35 U.S.C. 103(a) over Kaplan should be withdrawn. Rejected dependent claim 57, as well as objected to claim 56, are allowable at least for the reasons set forth above with respect to independent claim 53, from which they depend, as well as for their added features.

Independent claim 71 recites, *inter alia*, wherein at least one of said plurality of microinfusion catheters is moveable within said macrocatheter. As set forth above, Kaplan

neither discloses nor suggests such features. More specifically, the lumens 126 disclosed by Kaplan are clearly a fixed part of the structure of the infusion sleeve 112, and thus are not moveable within the catheter 110. Further, as set forth above, the infusion catheter disclosed by Kaplan is specifically designed for infusing liquid chemicals into the artery of a patient after an angioplasty procedure, and Kaplan does not disclose or suggest that his infusion catheter could be easily or readily adapted for use in the brain, nor that it would be beneficial to do so.

For at least these reasons, it is respectfully submitted that independent claim 71 is allowable over Kaplan, and thus the rejection of independent claim 71 under 35 U.S.C. 103(a) over Kaplan should be withdrawn. Rejected dependent claims 73, 77, and 79, as well as objected to claims 72 and 78, are allowable at least for the reasons set forth above with respect to independent claim 71, from which they depend, as well as for their added features.

The subject matter of allowable claim 93 has been incorporated into independent claim 92. Accordingly, it is respectfully submitted that independent claim 92 is allowable over Kaplan, and thus the rejection of independent claim 92 under 35 U.S.C. 103(a) over Kaplan should be withdrawn. Rejected dependent claim 94 is allowable at least for the reasons set forth above with respect to independent claim 92, from which it depends, as well as for its added features.

The Office Action rejects claims 9-10, 43, 59, 74, 83, and 89 under 35 U.S.C. 103(a) as being unpatentable over Kaplan in view of Scheinman et al., U.S. Patent No. 5,429,131 (hereinafter "Scheinman"). The rejection is respectfully traversed.

Dependent claims 9-10, 43, 59, and 74 are allowable over Kaplan at least for the reasons set forth above with respect to independent claims 8, 53, and 71, from which they respectively depend, as well as for their added features. Further, Scheinman is merely cited to teach the use of sensing electrodes and magnetized electrodes, and thus fails to overcome the deficiencies of Kaplan. Accordingly, it is respectfully submitted that dependent claims 9-10, 43, and 59, as well as objected to claim 44, which depends from claim 43, and objected to claims 75-76, which depend from claim 74, are allowable over the applied combination, and thus the rejection of claims 9-10, 43, 59, and 74 under 35 U.S.C. 103(a) over Kaplan and Scheinman should be withdrawn.

Independent claim 83 recites, *inter alia*, wherein at least one microinfusion catheter of said plurality of microinfusion catheters comprises a plurality of drug delivery ports arranged to deliver a drug to a separate site within the hypothalamus. As set forth above, Kaplan neither discloses nor suggests such features.

More specifically, the four lumens 126 and their respective ports 128 are fixed within the structure of the catheter disclosed by Kaplan and deliver a solution to a target site. Thus, the ports 128 may not be arranged to deliver a drug to a separate site within the hypothalamus, as recited in independent claim 83. Additionally, as set forth above, the infusion catheter disclosed by Kaplan is specifically designed for infusing liquid chemicals into the artery of a patient after an angioplasty procedure, and Kaplan does not disclose or suggest that his infusion catheter could be easily or readily adapted for use in the brain, nor that it would be beneficial to do so.

Further, Scheinman is merely cited to teach the use of sensing electrodes and magnetized electrodes, and thus fails to overcome the deficiencies of Kaplan.

For at least these reasons, it is respectfully submitted that independent claim 83 is allowable over the applied combination, and thus the rejection of independent claim 83 under 35 U.S.C. 103(a) over Kaplan and Scheinman should be withdrawn. Objected to claim 84 is allowable at least for the reasons set forth above with respect to independent claim 83, from which it depends, as well as for its added features.

Independent claim 89 recites, *inter alia*, wherein at least one microinfusion catheter of the plurality of microinfusion catheters is moveable. As set forth above, Kaplan neither discloses nor suggests such features. Further, Scheinman is merely cited to teach the use of sensing electrodes and magnetized electrodes, and thus fails to overcome the deficiencies of Kaplan.

Accordingly, it is respectfully submitted that independent claim 89 is allowable over the applied combination, and thus the rejection of independent claim 89 under 35 U.S.C. 103(a) over Kaplan and Scheinman should be withdrawn. Objected to claims 90-91 are allowable at least for the reasons set forth above with respect to independent claim 89, from which they depend, as well as for their added features.

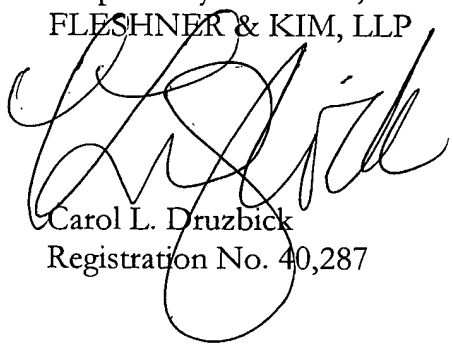
Added dependent claims 95-98 are allowable over the applied prior art in view of their respective dependency on independent claims 8, 80, 82, and 83, as well as for their added features.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned attorney, **Carol L. Druzbick**, at the telephone number listed below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
FLESHNER & KIM, LLP



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